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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,565	12/21/2001	Oscar M. Bassinsan	6739	9996

22922 7590 05/21/2003

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EXAMINER

JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,565

Applicant(s)

BASSINSON, OSCAR M.

Examiner

Robert M. Joynes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 34 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used to properly identify any particular material or product." MPEP 2173.05 (u). Claims 31, 34 and 36 contain at least two trademarks in the members of the Markush group for each claim, namely Zofran and Pepcid. It is suggested that applicants amend the claims to recite the generic name for these drugs.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellstrom alone or in combination with BE 637363A. Hellstrom teaches an individualized pharmaceutical package comprising a relatively rigid backing member with a depression therein and an item for dispensing positioned with a central depressed area of said backing member and a membrane stretched over the item and joined at the periphery of the backing member (Col. 5, lines 46-60; Col. 6, lines 9-18; Col. 14, Claims 1 & 2). The reference teaches that the item included in the package can be a tablet, capsule, pill, liquid, semiliquid or powder (Col. 5, lines 46-60; Col. 8, lines 51-75). The liquids, semiliquids and powder are contained in a cup attached to the backing member (Col. 8, lines 51-75). Hellstrom does not limit the active agents that can be administered with such a package system.

Hellstrom does not expressly teach that the powder formulation is absorbed onto the backing member with the use of a binding agent. Hellstrom further does not expressly teach the exact active agents recited in the instant claims to be administered from the package. Hellstrom further does not teach that the backing member is in the size and shape of a credit card.

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It is the position of the Examiner that the particular active agent to be dispensed with said package system is not critical. In addition, the size and shape of the backing member also does not appear to be critical. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dispense various active agent from a package system such as described by Hellstrom wherein the size and shape of the backing member is varied. One would be motivated to vary the drug to be dispensed to prepare different individualized packages for the various drugs or actives that one would need to carry with them. In addition, one would vary the size and shape of backing member for aesthetic reasons as well as for convenience, depending upon the form of the active agent. It is the position of the Examiner that these are limitations that would be routinely determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations.

Further, it is the position of the Examiner that the attaching of the powder directly to the card with a binding agent is also not critical. The prior art teaches various forms of the package system that include tablets, or capsule or powders. The Examiner sees no criticality in binding the drug directly to backing member. The prior art appears to teach the same general concept of the package system – a backing member, an active formulation and a film covering the active formulation. The prior art provides a package that is easily transported and provides easy administration of the formulation contained within the package.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to vary the form of the active composition that is contained within the package of the Hellstrom. One of ordinary skill would be motivated to do so to most effectively deliver the desired active agent to the host.

Therefore, the instant claims are rendered obvious over the prior art absent a clear showing of unusual or unexpected results. The results must be those that accrue from the specific limitations.

In addition, Hellstrom can be combined with BE 637363 A (hereinafter '363) reference. The teachings of Hellstrom are discussed above. Hellstrom does not expressly teach that the active agent is attached to the backing member with a binding agent.

'363 teaches a medicament composition in which an active agent is absorbed or attached to inert fiber of paper with a water-soluble binding agent (See abstract). The paper product can be provided in the form of a stamp or in other convenient forms so that any dose may be conveniently administered.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach an active agent with a binding agent to a backing member made from paper to administer a desired drug.

One would have been motivated to do so to reduce research time and research costs in developing a tablet or capsule formulation.

Again, it is the position of the Examiner that the particular active agent to be dispensed with said package system is not critical. In addition, the size and shape of

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the backing member also does not appear to be critical. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dispense various active agent from a package system such as described by Hellstrom wherein the size and shape of the backing member is varied. One would be motivated to vary the drug to be dispensed to prepare different individualized packages for the various drugs or actives that one would need to carry with them. In addition, one would vary the size and shape of backing member for aesthetic reasons as well as for convenience, depending upon the form of the active agent. It is the position of the Examiner that these are limitations that would be routinely determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations.

Therefore, the instant claims are rendered obvious over Hellstrom in combination with '363.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joyner whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
May 19, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600